Sulfolane Toxicity Meeting

Monday, March 14, 2011, 10:30 am – 11:30 am Alaska time

Attendees

Selene Chou, ATSDR Division of Toxicology and Environmental Medicine, Chair ATSDR MRL Workgroup

Jim Durant, ATSDR Emergency Response Coordinator with DTEM

Marcia Bailey, EPA Region 10

Chris Cubbison, EPA, National Center for Environmental Assessment, Associate Director for Superfund Technical Support Center (STSC)

Pauli Undesser, The Water Quality Association (WQA), Director of Regulatory and Technical Affairs

Meg Whittaker, ToxServices

Chris Schlosser, ToxServices

Brandon Perkins, EPA Region 10, Site Assessment Manager

Dan Petersen, EPA NCEA-ORD, Chemical Manager for the Sulfolane PPRTV

Cassie Kirk, DHSS, EPHP Health Assessor

Ann Farris AK Dept. of Environmental Conservation (ADEC), Contaminated Sites Project Manager

Stephanie Pingree Buss, SPB Consulting – consultant for ADEC

Meeting Summary

1) Introductions
2) EPA PPRTV status
    a) Dan Petersen – Managing assessment of sulfolane for EPA
    b) Status
        i) Go to internal peer-review next week (3/23)
        ii) Then will prepare external-review draft
            (1) At this stage will then be able to share document with group
    c) Principle study – Huntingdon Life Sciences for oral reference value
        i) HLS study in process of being peer-reviewed
        ii) For studies not peer-reviewed, the reference value would need to appear in the appendix of the PPRTV document
            (1) Shows less certainty in the value by putting it in the appendix
            (2) Peer-reviewed studies, the value can be in the body of the text
                (a) Comments and response from the peer-review will be publicly available

iii) For the final PPRTV document – peer review should be complete and oral reference value will be moved from appendix to body of the text
    (1) Value will not change
iv) Will be able to develop an oral PPRTV based on HLS study and an inhalation value based on Andersen study
    (1) Endpoint – white blood cell changes
        (a) Observed in HLS study
        (b) Zhu saw same endpoint
            (i) using Zhu as a backup study
        (c) HLS was more sensitive endpoint resulting in a lower value

3) ATSDR Health Consultation status
    a) Jim Durant, lead contact for sulfolane evaluation
    b) Status
        i) Received external-review comments
        ii) In internal clearance process
            (1) Reviewed through Branch Chief
            (2) At Division Director for review
        iii) Value based on Zhu study
            (1) ATSDR's Peer-Review group felt guinea pig more sensitive animal
        iv) Next week or two will be able to provide draft copy to DEC, DHSS, EPA, WQA contacts
        v) Talked with China CDC contact who reviewed Zhu study
            (1) China contact didn't feel it would be possible to reach researchers
            (2) Looked at original Chinese manuscript
                (a) Addition information – felt 90-day test used oral gavage dosing
        vi) Timeline
            (1) 2-4 weeks for document release

4) Water Quality Association
    a) Pauli Undesser
        i) WQA – trying to come up with a protocol for treatment system to reduce sulfolane in drinking water
            (1) Developing target for sulfolane in drinking water/treatment systems
        ii) Meg Whittaker
            (1) Total allowable concentration (TAC) report
                (a) Based on EPA risk assessment protocol
                (b) Difference - allows for qualitative evaluation – like FDA Red Book
            (2) TAC = 70 ug/L
                (a) Based on decreased white-blood cell counts in rats
                (b) Reviewed Flint Hills/ToxStrategies report
                    (i) Did not use relative source contribution factor
                    (ii) Used benchmark dose modeling of HLS
                    (iii) Some unjustified use of UF and statistics to develop a high DW/RfD level
                (c) Used HLS Study

(i) UF = 300
(ii) Did not add UF for no chronic study (2 year study)

(d) Assumes 2 L of water / 70 kg weight
(e) Significant data gaps in tox data so felt modeling was inappropriate; therefore used NOAEL approach
(f) Zhu study lacking details that would results in overly conservative value
(g) Similar drinking water values for adults as ATSDR's value
(i) ATSDR also developed infant levels
(h) EPA tried benchmark dose modeling but did not get a good fit

b) Process
i) Draft – To be shared with group
(1) Comments can be sent to WQA/Pauli
(a) Comments to Pauli by middle of April
ii) Review Panel – April 1st
(1) Panel will review and provide comments at that time

c) Action Item: Stephanie Pingree Buss send report to group
i) No citing, use or distribution of document beyond this group
ii) Will also send a copy of Annex A

d) Major Data gaps
i) Lymphopenia endpoint
(1) Very inducible
(2) Animals may be more susceptible or stress induced
(3) Is it biologically significant?
(a) Made assumption is it for protection of public health

5) Next Steps
a) Next call in 4-6 weeks
b) DEC will schedule meeting